

REMARKS

Claims 1-4, 11, 13, 14 and 22 are currently pending in the application. After entry of this amendment, claims 1-4, 11, 13, 14 and 22-26 will be pending in the application. Claims 4 and 22 are allowed and claims 1-3, 11, 13 and 14 are currently rejected.

Applicants included an amendment to claims 1 and 11 in the Amendment Under 37 C.F.R. §1.111 filed May 13, 2004, in the present application. However, in light of the Examiner Interview of June 2, 2004, Applicants have further amended claims 1 and 11, and added new claims 23-26.

Specifically, the 51 kDa limitation has been deleted from claims 1 and 11.

Claims 1 and 11 have also been amended to recite polypeptides encoded by a nucleic acid sequence that hybridizes to the complement of SEQ ID NO: 7 under highly stringent conditions of 6X SSC, 0.1% SDS, and 68°C. This amendment is supported in the specification at page 70.

Finally, new claims 23-26 have been added. Claims 23 and 24 recite polypeptides of claim 1 derived from genera and species set forth at Table 6 on page 45 of the specification. Claims 25 and 26 recite methods of claim 11 for producing polypeptides from the microorganisms described above. Claims 23-26 are supported throughout the specification, particularly in the Examples.

Applicants respectfully request that the Examiner enter the instant Supplemental Amendment and amend the claims as set forth herein.

I. Claims 1 and 11

In the Office Action of January 13, 2004, claims 1 and 11 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with both the written description and the enablement requirements.

A. Molecular Weight

In the Office Action, the Examiner contended that the specification does not support a polypeptide having a molecular weight (MW) in the range of 47 - 51 kDa. In the Amendment filed May 13, 2004, claims 1 and 11 were amended to recite polypeptides with “an approximate molecular weight of about 47 kDa as determined by SDS PAGE and about 51 kDa as determined by sequence-based algorithm.”

In the interview, the Examiner indicated that the phrase “about 51 kDa as determined by sequence-based computer algorithm” might raise “new matter” issues under 35 U.S.C. § 112, first paragraph, because there is no support in the specification for determination of MW by computer algorithm. Furthermore, the Examiner stated that the term “about” should be deleted, because when the MW of a protein is calculated based on amino acid sequence, the resulting MW value is not variable.

Accordingly, as noted above, claims 1 and 11 have been amended herein to recite polypeptides with an approximate molecular weight of about 47 kDa as determined by SDS-PAGE. The 51 kDa limitation has been deleted from the claims.

B. Hybridization Conditions

In the Office Action, the Examiner contended that the specification does not support the entire genus of polypeptides claimed, because the claimed genus encompasses species with varying function and structure.

With regard to function, Applicants argued in the Amendment filed May 13, 2004, that a person of ordinary skill in the art would expect that the substrate specificity of *Aspergillus fumigatus* diglycosidase is the same or similar to that of the enzyme isolated from the other recited sources. During the interview, the Examiner indicated that he found these arguments persuasive.

Applicants also argued that because highly stringent hybridization conditions yield structurally similar genes, a person of ordinary skill in the art would not expect substantial structural variation between the diglycosidase enzyme of *Aspergillus fumigatus* and the enzyme encoded by the hybridizing genes of the other microorganisms.

In the interview, the Examiner suggested that including hybridization conditions in claims 1 and 11 might be sufficient to overcome the outstanding written description and enablement rejections.

Accordingly, as noted above, claims 1 and 11 have been amended herein to recite polypeptides wherein the polypeptide is encoded by a nucleic acid sequence that hybridizes to the complement of SEQ ID NO: 7 under highly stringent conditions of 6X SSC, 0.1% SDS, and 68°C.

Applicants respectfully submit that claims 1 and 11 are fully described and enabled, and therefore request reconsideration and withdrawal of the written description and enablement rejections.

II. Claim 3

In the Office Action, the Examiner contended that the variants recited in claim 3 are not enabled, because the positions within an amino acid sequence where modification can be made with a reasonable expectation of success in obtaining a 95% homologous variant having the desired activity are limited, and the result of such modifications is highly unpredictable.

In response, Applicants argued in the amendment that the specification and the art disclose routine methods for synthesizing variants and isolating variants, and Applicants have provided assays for detecting the function of such variants. Furthermore, due to the structural similarity of the members of the genus recited in claim, one of ordinary skill in the art would expect that a substantial number of variants would possess the claimed enzymatic activity.

In the interview with the Examiner, the Examiner stated that he still had concerns regarding whether creating and identifying enzymatically active variants of SEQ ID NO: 8 might require undue rather than merely routine experimentation.

Applicants submit herein that both obtaining genetically engineered variants, and isolating naturally-occurring variants, involves routine rather than undue experimentation. Specifically, using DNA represented by SEQ ID NO: 7 as a starting material, it would be easy to modify the amino acid sequence of the encoded protein in order to obtain a protein having at least 95% homology to SEQ ID NO: 8. Furthermore, a person of ordinary skill in the art could

readily isolate genes encoding the variants of the present invention, by screening microorganisms capable of producing the recited enzyme using standard Southern blotting techniques, with SEQ ID NO: 7 as a probe, under stringent hybridization conditions.

Finally, although a person of ordinary skill in the art would not necessarily be able to predict which particular amino acid modifications would lead to a functional polypeptide, they would recognize that a genus of variants with at least 95% homology to SEQ ID NO: 8 would be reasonably likely to include at least some functional polypeptides. Practitioners in this art would be prepared to screen negative variants in order to find polypeptides that have the desired activity. Thus, even an arguably low success rate would not demonstrate a high level of unpredictability or unreliability in the art.

III. Claims 23-26

As noted above, new claims 23-26 recite polypeptides and methods for producing polypeptides isolated from microorganisms listed at Table 6 and described throughout the specification.

For at least the reasons set forth at pages 14-16 and 18-19 of the amendment filed May 13, 2004 in this application, Applicants submit that new claims 23-26 are fully described and enabled by the specification.

VI. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Supplemental Amendment Under 37 C.F.R. § 1.111
U.S. Appln. No. 09/806,413

Attorney Docket No.: Q63731

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

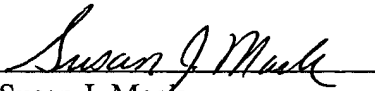
Respectfully submitted,

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

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CUSTOMER NUMBER


Susan J. Maek
Registration No. 30,951

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